

of his or her right to review information about the individual that is collected and maintained under this part to assure its accuracy. Licensees and other entities shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is documented by licensees and other entities about the individual.

(d) Licensees and other entities shall ensure that only correct and complete information about individuals is retained and shared with other licensees and entities. If, for any reason, the shared information used for determining an individual's eligibility for authorization under this part changes or new information is developed about the individual, licensees and other entities shall correct or augment the shared information contained in the records. If the changed or developed information has implications for adversely affecting an individual's eligibility for authorization, a licensee and other entity specified in § 26.3(a) and, as applicable, (c) and (d), who has discovered the incorrect information, or develops new information, shall inform the reviewing official of any FFD program under which the individual is maintaining authorization of the updated information on the day of discovery. The reviewing official shall evaluate the information and take appropriate actions, which may include denial or unfavorable termination of the individual's authorization.

§ 26.713 Recordkeeping requirements for licensees and other entities.

(a) Each licensee and other entity who is subject to this subpart shall retain the following records for at least 5 years after the licensee or other entity terminates or denies an individual's authorization or until the completion of all related legal proceedings, whichever is later:

(1) Records of self-disclosures, employment histories, and suitable inquiries that are required under §§ 26.55, 26.57, 26.59, and 26.69 that result in the granting of authorization;

(2) Records pertaining to the determination of a violation of the FFD policy and related management actions;

(3) Documentation of the granting and termination of authorization; and

(4) Records of any determinations of fitness conducted under § 26.189, including any recommendations for treatment and followup testing plans.

(b) Each licensee and other entity who is subject to this subpart shall retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of FFD training and examinations conducted under § 26.29; and

(2) Records of audits, audit findings, and corrective actions taken under § 26.41.

(c) Licensees and other entities shall ensure the retention and availability of records pertaining to any 5-year denial of authorization under § 26.75(c), (d), or (e)(2) and any permanent denial of authorization under § 26.75(b) and (g) for at least 40 years or until, on application, the NRC determines that the records are no longer needed.

(d) Licensees and other entities shall retain any superseded versions of the written FFD policy and procedures required under §§ 26.27, 26.39, and 26.203(b) for at least 5 years or until completion of all legal proceedings related to an FFD violation that may have occurred under the policy and procedures, whichever is later.

(e) Licensees and other entities shall retain written agreements for the provision of services under this part for the life of the agreement or until completion of all legal proceedings related to an FFD policy violation that involved those services, whichever is later.

(f) Licensees and other entities shall retain records of the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under § 26.31(b)(1)(i), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later.

(g) If a licensee's or other entity's FFD program includes tests for drugs in addition to those specified in this part, as permitted under § 26.31(d)(1), or uses more stringent cutoff levels than those specified in this part, as permitted under § 26.31(d)(3), the licensee

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or other entity shall retain documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under § 26.31(d)(1)(i) and (d)(3)(iii)(C), respectively, for the time the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later.

§ 26.715 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services.

(a) Collection sites providing services to licensees and other entities who are subject to this subpart, licensee testing facilities, and HHS-certified laboratories shall maintain and make available documentation of all aspects of the testing process for at least 2 years or until the completion of all legal proceedings related to a determination of an FFD violation, whichever is later. This 2-year period may be extended on written notification by the NRC or by any licensee or other entity for whom services are being provided.

(b) Documentation that must be retained includes, but is not limited to, the following:

(1) Personnel files, including training records, for all individuals who have been authorized to have access to specimens, but are no longer under contract to or employed by the collection site, licensee testing facility, or HHS-certified laboratory;

(2) Chain-of-custody documents (other than forms recording specimens with negative test results and no FFD violations or anomalies, which may be destroyed after appropriate summary information has been recorded for program administration purposes);

(3) Quality assurance and quality control records;

(4) Superseded procedures;

(5) All test data (including calibration curves and any calculations used in determining test results);

(6) Test reports;

(7) Records pertaining to performance testing;

(8) Records pertaining to the investigation of testing errors or unsatisfactory performance discovered in quality control or blind performance testing, in the testing of actual specimens, or

through the processing of appeals and MRO reviews, as well as any other errors or matters that could adversely reflect on the integrity of the testing process, investigation findings, and corrective actions taken, where applicable;

(9) Performance records on certification inspections;

(10) Records of preventative maintenance on licensee testing facility instruments;

(11) Records that summarize any test results that the MRO determined to be scientifically insufficient for further action;

(12) Either printed or electronic copies of computer-generated data;

(13) Records that document the dates, times of entry and exit, escorts, and purposes of entry of authorized visitors, maintenance personnel, and service personnel who have accessed secured areas of licensee testing facilities and HHS-certified laboratories; and

(14) Records of the inspection, maintenance, and calibration of EBTs.

§ 26.717 Fitness-for-duty program performance data.

(a) Licensees and other entities shall collect and compile FFD program performance data for each FFD program that is subject to this subpart.

(b) The FFD program performance data must include the following information:

(1) The random testing rate;

(2) Drugs for which testing is conducted and cutoff levels, including results of tests using lower cutoff levels, tests for drugs not included in the HHS panel, and any special analyses of dilute specimens permitted under § 26.163(a)(2);

(3) Populations tested (*i.e.*, individuals in applicant status, permanent licensee employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (*i.e.*, individuals in applicant status, permanent licensee employees, C/Vs);

(5) Conditions under which the tests were performed, as defined in § 26.31(c);

(6) Substances identified;

(7) Number of subversion attempts by type;